OCT 1 - 2004

K042467

510(K) SUMMARY

(As required by 21 CFR 807.87(h))

Identification of Submitter

Submitter:	M. Alaine Medio, RAC Senior Regulatory Affairs Specialist CTI Molecular Imaging, Inc. 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(865)218-2703
Fax Number:	(865)218-3019
Date of Submission:	

Identification of the Product

Device Proprietary Name:	LSO PET/CT HiRez 64
Common Name:	Combination Positron Emission Tomography (PET) and Computed Tomography (CT) System
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to which Equivalence is Claimed

Device	Manufacturer	510(k) Number
LSO PET/CT HiRez 16	CTI PET Systems (CPS)	K033431
Somatom Sensation 64 CT	Siemens Medical Technologies	K040668

Device Description:

The CPS LSO PET/CT Hi-Rez 64 system is a combined Positron Emission Tomography and X-Ray Computed Tomography scanner. The system is an addition to the current CPS PET/CT Hi-Rez Family of PET/CT systems and is essentially identical to the commercially available CPS LSO PET / CT Hi-Rez 16 system (K033431) with the exception of a higher resolution CT system – Siemens 64 slice CT (K040665).

The system is designed for whole-body oncology, neurology and cardiology examinations. The PET / CT 64 gantry system consists of a separate PET and CT gantry that retain their independent scanning mechanisms, including mechanical and electrical components. In addition, it provides registration and fusion of high-resolution metabolic and anatomic information from the two major components of the system, the Accel Hi-Rez LSO PET scanner and the Siemens Somatom Sensation 64 CT.

The difference between the current Siemens Sensation 16 used in the commercially available CPS PET/CT systems is the number of slices acquired

per rotation. Current PET/CT's are capable of acquiring 16 slices per rotation while the Sensation 64 is capable of acquiring 64 slices per rotation, thus increasing the resolution of the acquired CT scan.

Indications for Use:

The CPS LSO PET/CT HiRez 64 system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. The LSO PET/CT scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

The PET and the CT functions of this system can also be used in combination to provide high resolution, noise free CT attenuation correction maps for PET images and, additionally, utilized to produce fused CT and PET images, providing detailed anatomic and metabolic function information in a single image.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube and the simultaneous translation of the patient.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Ms. M. Alaine Medio, RAC
Senior Regulatory Affairs Specialist
CPS Innovations
810 Innovation Drive
KNOXVILLE TN 37932

Re: K042467
Trade/Device Name: LSO PET/CT HiRez 64 System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: September 10, 2004
Received: September 15, 2004

Dear Ms. Medio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K042467

Device Name: LSO PET/CT HiRez 64 system

Indications for Use:

The CPS LSO PET/CT HiRez 64 system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. The LSO PET/CT scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042467

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)